REMARKS

Telephone Communication

The undersigned would like to thank the Examiner's supervisor, Sreeeni Padmanabhan, for the helpful telephone discussion on May 13, 2009. During that discussion, a telephonic interview was scheduled for July 14, 2009, coincident with Examiner McMiliian'e return to the Office and review of this Reply. The undersigned requests that Examiner McMillian contact the undersigned about one week prior to the interview to decide a suitable time for conducting the interview.

Rejection of Claims 2-3 and 8-15 Under 35 U.S.C. § 103(a)

The Examiner rejected Claims 2-3 and 8-15 under 35 U.S.C. § 103(a) as being unpatentable over Keim (U.S. Patent No. 3,700,623) in view of McTaggart (U.S. Patent No. 5,462,730). In particular, the Examiner stated that although Keim does not teach that a polydiallylamine homopolymer can be used as a pharmaceutical composition, one of skill in the art would recognize Kiem's **polydiallylamine** homopolymers as suitable for a pharmaceutical composition, because McTaggart demonstrates that **polyallylamine** polymers can be formulated as such. Applicants disagree with the Examiner's assertions.

Applicants' Invention

Applicants' claims are directed to a pharmaceutical composition comprising a unit dosage form of a crosslinked polydiallyamine homopolymer, which is free of alklylated amine monomers, and a pharmaceutically acceptable carrier. Each of the two independent claims specify the structure of the unit dosage form (i.e., Claim 2 specifies a tablet and Claim 8 specifies a capsule).

Kiem

As acknowledged by the Examiner, Keim does not explicitly teach polydiallyamine homopolymers as pharmaceutical compositions. Rather, Keim teaches the use of water soluble polydiallylamine polymers as wet strength agents for paper, that also provide dry strength to paper. At Col 3. lines 63-75, Keim teaches that the aqueous resins are applied to the paper by

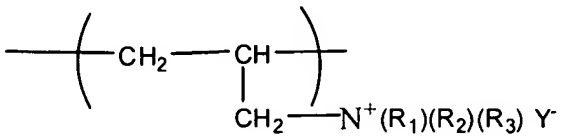
tub application or by spraying of an aqueous resin solution having a solids content of 15% or less. Alternatively, this aqueous solution of resin can be added to an aqueous suspension of paper stock before paper sheet formation. There is no teaching or suggestion in Keim that the water soluble resin materials used to provide a paper with superior wet and dry strengths (e.g., wrapping paper), be used to prepare a pharmaceutical composition in a solid form, nevermind as a solid unit dosage in the form of a tablet or a capsule.

More specifically, the aqueous resin solution of Keim would not motivate one of ordinary skill in the art to prepare a pharmaceutical composition in the unit dosage form of a tablet or a capsule. In fact, preparation of a solid unit dosage form would be contrary to the teachings of Keim, which require an aqueous resin solution to strengthen paper. In other words, one of ordinary skill in the art would not be motivated to substitute a capsule or tablet for the aqueous resin solution of Keim, because such a form would destroy the ability to apply the resin to paper, because one cannot spray a tablet or capsule onto paper or dip paper in a tablet. Furthermore, the use of the resin prior to paper formation requires the addition of the aqueous resin solution, not a tablet or capsule, to the paper stock suspension.

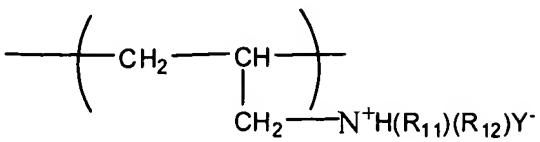
The Examiner relies on McTaggart to cure the deficiencies of Keim. Applicants submit that the teachings of McTaggart do not cure the deficiencies of Kiem. McTaggart is insufficient because the quaternary ammonium-containing polymeric allylamine derivatives described in McTaggart, are so structurally diverse from the polymers of Kiem that one of ordinary skill in the art would not recognize from McTaggart that the polydiallylamine polymers of Kiem could be use in a pharmaceutical form.

McTaggart

The polymers of McTaggart are insoluble swellable polymeric allylammonium derivatives having a quaternary propylammonium monomeric unit of the following formula:



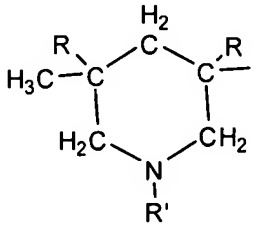
a crosslinking unit and a propylamine unit of the formula:



where the R groups can be alkyl or phenyl moieties.

It is made clear in McTaggart that the presence of the quaternary ammonium groups form the core basis for the invention (Col. 1, lines 64-67), providing polymers with the desired activity to reduce plasma sterol levels at low doses and with minimal side effects. The quaternary ammonium group is further specified as a quaternary propylammonium at a minimum level of 10 mole percent, with 60 mole percent being preferred (Col. 3, line 60-66). As such, contrary to the Examiner's assertions that McTaggart generally teach that polyallyamine resins are useful in a pharmaceutical composition, McTaggart teaches that a very specific polyallylamine, in which the nitrogen of the repeat unit is a quaternary propylammonium, can be useful as a pharmaceutical.

The polydiallylamine polymers of Keim having the following cyclic monomer unit (McTaggart's monomer unit is non-cyclic) and no quaternary propylammonium (required by McTaggart):



where R is hydrogen or alkyl and R' is hydrogen, alkyl or substituted alkyl.

Based on the significant structural diversity in the monomers unit of Keim and McTaggart, one of ordinary skill in the art would not be motivated to substitute the polydiallylamine of Keim for the quaternary propylammonium-containing polymer of McTaggart, especially since McTaggart predicates its invention on the presence of a quaternary propylammonium structural unit. More specifically, substitution of the quaternary propylammonium-containing polymer of McTaggart with the polydiallylamine polymer of Keim would not be recognized by one of ordinary skill in the art as a routine substitution of one polymer for another to obtain predictable results, because of the significant structural diversity between the described polymers and the fact that Kiem provides paper processing as its sole use.

Furthermore, McTaggart provides no suggestion or teaching that polymers other than the non-cyclic, hydrophobic quaternary propylammonium-containing polymers are suitable for use in a pharmaceutical compositions. As such, one would not be motivated to use other polymers in the pharmaceutical compositions of McTaggart, and certainly not the structurally diverse polydiallylamine polymers of Keim, useful for paper processing.

Applicants believe all pending claims meet the requirement of 35 U.S.C. 103(a) and are patentable over the teachings of Keim either alone or in combination with McTaggart. Reconsideration and withdrawal of the rejection are respectfully requested.

Disclosure Statement

An Information Disclosure Statement is being filed concurrently herewith. Entry of the IDS is respectfully requested.

CONCLUSION

In view of the above remarks, it is believed that all claims are in condition for allowance, and it is respectfully requested that the application be passed to issue. The Examiner's attention is directed to the subheading "Telephone Communication" above regarding next steps in expediting prosecution of this case.

Respectfully submitted,

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